

NOV 16 2006

REMARKS

Claims 1 - 5 and 7 - 9 were rejected under Section 102 as anticipated by patent 6,436,119 to Erb, and claim 10 under Section 103 as obvious in light of Erb. The rejections are respectfully traversed, particularly in light of the amendments made above, and reconsideration and withdrawal are earnestly solicited.

The object of the tool of this invention is to provide a uniform or nearly uniform cylindrical bore in bone, especially to enable soft tissue graft repair of the anterior cruciate ligament, which is commonly torn free in sports injuries and the like. A cylindrical tunnel is first drilled to receive the terminations of the graft ligament. However, the cancellous bone surrounding the preferred location of these bores is sometimes too soft and spongy to hold threaded fasteners and the like, as is needed to make a secure repair. To improve the holding power of the bone, it is desired to compact the bone surrounding the tunnel; that is, it is desired to expand the cylindrical tunnel radially outwardly, forming a larger-diameter cylindrical bore which will receive the ends of the graft and hold fasteners securely. The present invention provides a tool for expanding the cylindrical tunnel outwardly while retaining its generally cylindrical shape, compacting the cancellous bone surrounding the tunnel and forming a larger, essentially permanent bore, so that the graft end and fastener(s) can be securely attached.

The tool of the invention, as recited in claim 1 as amended, comprises a plurality of segments, each comprising an elongated distal portion and a proximal hub portion, and a knob for receiving the hub portions of each of the segments. When assembled, the distal segments make up a

cylindrical member for fitting snugly in the initial bore drilled in the bone. The knob and the hub of each segment cooperate so that the distal segments can only move radially inwardly and outwardly parallel to the axis of the cylindrical member; that is, the segments move outwardly while remaining parallel to one another, so that an enlarged but still cylindrical bore, surrounded by compacted cancellous bone, is formed. Claim 1 has also been amended to further clarify the use of the tool, that is, to enlarge a drilled tunnel by compacting the surrounding cancellous bone while forming a larger bore.

Erb, by comparison, shows a tool comprising a longitudinally partially split tube. As a central tapered member is drawn inwardly from its distal end, in the embodiment of Figs. 1 - 10, or urged outwardly, in Figs. 11 and 12, its tip forces the distal ends of the arms of the tube to be splayed outwardly. However, as their proximal ends are fixed, the arms necessarily undergo rotation about a transverse axis passing through the proximal ends of Erb's arms 60 and 62, at the proximal end 80 of slot 64. This produces a tapered anatomic space in the soft tissue being expanded, that is, spaces the surrounding tissue apart so that some other procedure can be carried out. While doubtless useful for the purpose intended, the Erb device would not be capable of compacting the cancellous bone surrounding a tunnel drilled therein to form a permanently enlarged, substantially cylindrical bore suitable for receiving a substantially cylindrical ligament-attaching plug or the like.

This distinction between the tool of the invention and the Erb tool has been emphasized by the amendment made hereby, i.e., to recite that the tool of the invention operates such that "said generally cylindrical member is increased in diameter as said segments move outwardly with

respect to said axis while remaining parallel to one another". Erb's segments do not move parallel to one another; they are splayed apart at their distal ends while remaining fixed at their proximal ends, such that a tapered space may be opened up in soft tissue. Thus, a cylindrical bore is simply not formed on operation of the Erb tool. Erb thus completely fails to anticipate claim 1 under Section 102, and there is no suggestion of modification of Erb that would suggest that claim 1 might be obvious in light thereof.

It is respectfully submitted that this amendment is merely clarificatory of the language in the claim previously and is appropriate for entry after final rejection.

In this connection, it should be noted that "generally cylindrical" or like terminology applied to the bore formed by the tool of the invention is intended to include the sort of bore shown in Fig. 2, i.e., to recognize that as the segments are forced outwardly the walls of the bore will tend to conform to the outer surfaces of the segments, which may be of smaller radius than that desired for the bore to be formed, and that it may be desirable to rotate the tool through on the order of 60 degrees and operate it again, to obtain a more uniform bore, as discussed in the application at p. 8, lines 14 - 26.

As noted, claim 1 has been amended to bring these aspects of the invention out more clearly, and it is respectfully submitted that claim 1 and the dependent claims are allowable.

With further reference to the dependent claims, it is to be noted that dependent claim 2 has been amended to recite that the knob comprises a tapered member fitting with a correspondingly-shaped lumen formed by the inner surfaces of the segments, such that when the tapered member

is moved distally along the lumen the segments are forced outwardly, while remaining parallel to one another. In the Figs. 1 - 10 embodiment, Erb shows splaying his segments by drawing a member proximally into the lumen between the segments, which is quite different. In his Figs. 11 and 12 embodiment, Erb shows splaying the tips of the split tube radially outwardly by urging a member outwardly along a lumen between the segments, which is closer. Nonetheless, at least insofar as claim 2 is dependent on claim 1, and recites that the segments remain parallel to one another, Erb fails entirely to meet claim 2 under Section 102 or to render it obvious under Section 103.

Erb also fails to show the structure of claim 3. Claim 3 recites that the tapered member includes two tapered surfaces joined by a cylindrical section and that the lumen comprises two angled surfaces joined by a cylindrical section. In his Figs. 1 - 10 embodiment, Erb shows a central member comprising an "arrowhead"-shaped tip having mating tapered surfaces without an intermediate cylindrical surface, while Erb's lumen is simply cylindrical. The outermost diameter of the arrowhead-shaped tip simply bears on the inner surface of the lumen, forcing the split members apart as it is drawn inwardly. Applicant's tapered member and lumen are cooperatively shaped so that the segments move outwardly parallel to one another as the tapered member is urged outwardly along the lumen. Erb's Fig. 11 embodiment shows a cooperatively shaped inner rod 144 and internal surfaces 162 and 166 of arms 148, 150, so that as the rod 144 is urged outwardly the arms are deflected. Nonetheless, Erb's inner rod and lumen do not show the claimed cooperating shapes, which involve separate angled or tapered surfaces spaced by parallel-sided section of the tapered member and lumen. Erb's rod simply tapers at its tip to cooperate with a

conical inner surface of the arms. Erb thus fails to meet claim 3 under either Section 102 or suggest it under Section 103. Applicant also reserves the right to argue that the Examiner's suggestion that Erb teaches "two angled cylindrical surfaces: one zero degrees" is inherently illogical, and that Erb does not in fact teach the tapered lumen and cooperating central member recited.

Claims 4 and 5 are dependent on claims 3 and 2 respectively and are likewise allowable. Further, Erb fails to show the details of the mechanism recited in claims 7 - 8 whereby the knob and hubs cooperate so that the segments are constrained to remain parallel to one another as they move inwardly and outwardly; these claims are likewise patentable over Erb.

Applicant would also point out that claim 10 recites that the garter spring is disposed around the hub portion of the segments, clearly distinguishing over the rubber band the Examiner suggests might be placed over the tip of the Erb device to prevent damage in shipping.

A Notice of Allowance is earnestly solicited.

Respectfully submitted,

11/16/06  
Dated



Michael de Angeli  
Reg. No. 27,869  
60 Intrepid Lane  
Jamestown, RI 02835  
401-423-3190